

Appendix A. Notification Handout for Intervention Sites



Are you a **Stroke Survivor**? **Will you help us?**

Your hospital is participating in a statewide study called the Comprehensive Post-Acute Stroke Services (COMPASS) Study. The purpose of the COMPASS Study is to determine the best ways to care for stroke survivors after they go home – to help stroke survivors find their way forward to recovery.

In the COMPASS Study, North Carolina hospitals are randomly assigned into two groups (similar to flipping a coin). One group of hospitals will provide patients with their usual post-stroke standard of care. The other group of hospitals will provide their usual post-stroke care with the addition of an evaluation by a Nurse Practitioner or Physician Assistant within two weeks of hospital discharge, during which patients will receive a plan of care that will be shared with their doctors, therapist and nurses.

You are in a hospital that has been randomly assigned to provide The COMPASS Model of post-stroke care which includes:

- A follow-up phone call 2 days after discharge
- A visit with a Nurse Practitioner or Physician Assistant 7-14 days after discharge
- A Plan of Care that will be shared with your other health care providers
- A follow-up phone call 30 days after discharge
- A follow-up phone call 60 days after discharge

Your hospital is committed to finding the best care model to improve health and recovery after experiencing a stroke. In addition to the COMPASS Care, you will continue to receive high quality care at this hospital and at your usual and planned follow up visits with your primary care doctors.

We are asking you to help us determine the best models of stroke care after hospital discharge. What to expect:

- The COMPASS team would like to call you in 3 months to ask questions about your recovery and satisfaction with your care.
- With your permission we will also mail a survey to your caregiver.
- All information you and your caregiver provide will be kept strictly confidential.

Whether or not you choose to participate in the survey, your hospital is committed to providing you with high quality care for your stroke recovery.

If you have any questions about the COMPASS Study, feel free to ask the stroke coordinator at this hospital or you can call the COMPASS Study team using the toll-free number below.

Hospital Stroke Coordinator:
COMPASS toll-free number:
COMPASS Study website: www.nccompass-study.org

Reached at:



Appendix B. Notification Handout for Control Sites

Are you a Stroke Survivor? Will you help us?

Your hospital is participating in a statewide study called the Comprehensive Post-Acute Stroke Services (COMPASS) Study. The purpose of the COMPASS Study is to determine the best ways to care for stroke survivors after they go home – to help stroke survivors find their way forward to recovery.

In the COMPASS Study, North Carolina hospitals are randomly assigned into two groups (similar to flipping a coin). One group of hospitals will provide patients with their usual post-stroke standard of care. The other group of hospitals will provide their usual post-stroke care with the addition of an evaluation by a Nurse Practitioner or Physician Assistant within two weeks of hospital discharge, during which patients will receive a plan of care that will be shared with their doctors, therapist and nurses.

You are in a hospital that has been randomly assigned to provide their usual standard of post-stroke care which includes:

- A hospital discharge summary that will go to the doctor that cares for you
- A discharge plan of care provided to you
- A follow up after hospitalization in the Stroke Clinic

Your hospital is committed to finding the best care model to improve health and recovery after experiencing a stroke. The COMPASS study will not interfere with the usual standard of care at this hospital or your usual and planned follow up visits with your primary care doctors.

We are asking you to help us determine the best models of stroke care after hospital discharge. What to expect:

- The COMPASS team would like to call you in 3 months to ask questions about your recovery and satisfaction with your care.
- With your permission we will also mail a survey to the family member, friend or neighbor whom you identify as helping you in your recovery (care helper).
- All information that you and the person you identify as your care helper provide will be kept strictly confidential.

Whether or not you choose to participate in the survey, your hospital is committed to providing you with high quality care for your stroke recovery.

If you have any questions about the COMPASS STUDY, feel free to ask the stroke coordinator at this hospital or you can call the COMPASS Study team using the toll-free number below.

Hospital Stroke Coordinator:
COMPASS toll-free number:
COMPASS Study website: www.nccompass-study.org



Appendix C. Written Consent Form at Follow-up Clinic



COMPASS STUDY Informed Consent and HIPAA Authorization

Your hospital is participating in a statewide study called the Comprehensive Post-Acute Stroke Services (COMPASS) Study. The purpose of the COMPASS Study is to determine the best ways to care for stroke survivors after they go home.

The PI for the COMPASS Study is Dr. Pamela Duncan at Wake Forest Baptist Medical Center. This study is funded by the Patient-Centered Outcome Research Institute (PCORI).

We would like to ask you for your consent and HIPAA authorization to keep a record of your personal health information and responses to the questions we asked you during the COMPASS telephone calls and this visit. This includes information from your recent hospitalization, visits to your doctor, and medications. We would like keep your responses to learn more about how we can improve the delivery of care to patients who have had a stroke. This information will be kept completely confidential and it will be kept in a secure place.

Your consent is completely voluntary. If you choose not to provide consent, you will still receive the same quality treatment and follow up. This medical facility may not condition (withhold or refuse) treating you on whether you sign this Authorization.

You may change your mind and withdraw your consent later. However, if you withdraw your consent, the organization may still use information that was previously collected about you. The health information listed above may be used by and/or disclosed to the study investigators at this site and others, study management centers, the study sponsor, and other groups, including federal agencies, which have a responsibility to assist in the oversight and management of the research study. This Authorization does not have an expiration date.

If you have any questions or if you would like to withdraw your consent, you can call us toll-free at _____ or if it easier, you can email us at: thecompassstudy@gmail.com.

Do you have any questions?

By signing below, you give permission to disclose your identifiable health information for the COMPASS research study. Would you like to give us permission to keep your data for research purposes?

Subject Name (Printed): _____

Subject Signature: _____ Date: _____ Time: _____ am pm

Person Obtaining Consent (Printed): _____

Person Obtaining Consent Signature: _____ Date: _____ Time: _____ am pm



The following page should be included if you are recruiting subjects with diminished mental capacity:

Legally Authorized Representative Name (Print): _____

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.)

Relationship to the Subject: _____

Legal Representative Signature: _____ Date: _____ Time: _____ am pm

Appendix D. Verbal Consent Information at 90 Day Telephone Survey

LABEL	VALUE	TEXT
INSTRUCTIONS		

CONSENT LANGUAGE PULLED OUT OF THE SCREENER

PURPOSE:

We are calling to follow up on his/her/your recent hospital stay at [HOSPITAL]. This hospital is participating in the COMPASS study which is a research study looking at how patients are doing after their stroke.

EXPLAIN [IF IRB_MON=1]:

[....] During this survey, you have the right to refuse to answer any questions you don't want to answer and you can stop participating at any time. [....]

SECURITY:

We wanted to also let you know that by participating you are giving us permission to keep a record of your responses to the survey. All of your responses and data will be strictly confidential and will be kept in a secure location.

RISK/BENEFIT:

We do not anticipate that participation in this survey involves any risks. There is also no direct benefit to you for participating.

PARTICIPATE/CONSENT:

Do I have your permission to continue with the survey?

THANK YOU:

Thank you for agreeing to participate in the COMPASS Study.

IF IRB_OFFER_NUM:

If you have any additional questions about the study, I can provide the numbers of the Wake Forest and UNC Chapel Hill Institutional Review Boards. Their job is to protect your rights and welfare as a research participant. They have reviewed and approved this study. Would you like those numbers?

The survey also has a link to the COMPASS website.

IRB_PI NUMBER [IF [IF IRB_OFFER_NUM=1]:

If you have any questions, comments or concerns about the study, please contact, anonymously if you wish, the Wake Forest IRB at _____ UNC Chapel Hill Institution Review Board. You can reach them at _____ or by email to _____. This information is also at the bottom of the survey that was mailed to you.